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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,467	09/17/2003	William Abraham	0207.04	4350

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,467	ABRAHAM ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,9,14-16 and 28-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 9, 14-16 and 28-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on January 10, 2005 wherein claims 1, 4, 9, 14-16 and 28-38 have been amended. Claims 2-3, 5-8, 10-13, and 17-27 are cancelled previously.

Currently, claims 1, 4, 9, 14-16 and 28-38 are pending in this application and under examination on the merits.

Priority

Note that Applicant' has presented a detailed analysis as to why the claimed subject matter has clear support in the parent application 08501664 filed July 12, 1996, under 35 U.S.C. 112 for the instant claims 1, 4, 9, 14-16 and 28-38 in the preliminary amendment submitted September 17, 2003 of this application (see Applicant's remarks filed January 10, 2005, page 4-5).Therefore, the filing date of the instant claims is deemed to be the filing date of the parent application 08501664 filing date, July 12, 1996.

Applicant's remarks filed January 10, 2005 with respect to the rejection made under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,735,273 in view of Janssen (EP 539625) further in view of JP 56137899 (of record) of record stated in the Office Action October 4, 2004 have been considered and are found persuasive to remove this particular rejection since the claims in U.S. Patent No. 6,735,273 in view of Janssen and

JP 56137899 are not seen to be obvious over the claims herein. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 9, 14-16 and 28-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted January 10, 2005 with respect to amended claims herein has been fully considered but is deemed to lack of adequate written description support for the claims as amended now, since the specification as originally filed does not provide support for "about 4.0% to about 40% by weight" of polyethylene oxide present in the instant hydrogel. The original specification clearly discloses "present in an amount in the range of more than 0.5% and less than 40% by weight, preferably 8 to 12% by weight when a humectant is also added, and preferably about 15 to 20% by weight when no humectant is added." (emphases added, see page 8 line 3-5 of the specification) and "polyethylene oxide is present in an amount of about 2% to

20%, more preferably about 10%." (emphases added, see page 29 line 13-14 of the specification).

The range now claimed "about 4.0% to about 40% by weight" is considered to the subgenus range of "0.5% and less than 40%" as originally described. The court held that "subgenus range was not supported by generic disclosure and specific example within the subgenus range"; See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); the court also held that "a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads" (see *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972). See also MPEP 2163.

Thus, the claimed range as amended now is seen to lack of adequate written description.

Applicant's amendment with respect to amended claim 16 has been fully considered but is deemed to insert new matter into the claims.

The omission of an essential element of the invention "the hydrogel patch" in claim herein is deemed to raise new matter issue, i.e., an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., >PIN /NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1353 (Fed. Cir. 2002). As noted in MPEP 2163, A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; In re Sus, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962).

In the instant case, the specification describes at page 27 line 3-20 about the structural support for "the hydrogel patch". Thus, "the hydrogel patch" herein is considered to be an essential and critical element of the claimed invention, clearly supported by Applicant's specification as originally filed.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 9, 14-16 and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (US 5,405,366) in view of Janssen (EP 539625) further in view of JP 56137899 (of record in the parent case) essentially for same reasons of record stated in the Office Action dated October 4, 2004.

Fox et al. discloses the hydrogel comprising (a) gel forming polymer material such polyethylene oxide (PEO) known as Polyox in an amount of 3-20 wt % of the total weight within the instant claim (see col.6 lines 63-68); (b) water in an amount from about 58 % to 96% wt of the total weight within the instant claim (see Table XIV at col.21-22;

Table XVI at col.23 line 28); (c) a pharmacologically active agent; (d) sodium chloride as an electrolyte in an amount 0.1-10 wt % of the total weight overlapping with the instant claimed range; (e) a phosphate buffer that maintains a pH of the hydrogel in pH of 7 (see col.21 lines 11-49); (f) a structural support embedded in the hydrogel such as non-woven fabric as the instantly claimed to form into patches (see abstract col.8 line 65 to col.9 line 10) ;(g) a humectant (see col.4 lines 59-64); (h) a biocide (see col.8.lines 6-24)

Fox et al. also discloses the same thickness and surface area in a range as the instant claimed (see col.8 line 60-64; col.9 line 6-10). Fox et al. also discloses the process of preparing of the hydrogels by cross-linking provided by radiaton wherein using the same cross-linking agent as the instant claimed such as N,N'-mehtylenebisscrylamide (see Table IX at col.17-18).

Fox et al. does not expressly disclose that a pharmacologically active agent in the hydrogel is glucose oxidase or mutarotase enzyme.

Janssen discloses that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, used for the same purpose as the instantly claimed (see abstract and col.1 lines 22-35; claim 1).

JP 56137899 teaches that combining mutarotase with glucose oxidase increases the sensitivity of glucose determination and the mechanism. See abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Fox et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Fox et al. since it is known that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, as the instantly claimed, according to Janssen.

Therefore, one of ordinary skill in the art would have reasonably expected that a known and art-recognized glucose oxidase used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, would have the same or substantially similar usefulness in the hydrogels of Fox et al., and that combining mutarotase with glucose oxidase would increase the sensitivity of glucose determination according to JP 56137899.

Response to Argument

Applicant's arguments filed January 10, 2005 with respect to this rejection made under 35 U.S.C. 103(a) as being unpatentable over Fox et al. in view of Janssen further in view of JP 56137899 in the previous Office Action October 4, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that "[n]one of the sensing electrodes of Fox, et al., is for electrochemical detection". Note that it is well settled that "intended use" of a composition or product such as a hydrogel herein, e.g., "for use in electroosmotic extraction of glucose across and electrochemical detection", will not further limit claims

drawn to a composition or product, so long as the prior art discloses the same or similar hydrogel comprising the same or similar ingredients in an effective amount as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Applicant asserts that "the Examiner did not completely address the differences between the prior art and the claims at issue". Contrary to Applicant's assertion, the Office Action clearly states that "Fox et al. does not expressly disclose that a pharmacologically active agent in the hydrogel is glucose oxidase or mutarotase enzyme." (see the previous Office Action, page 4, 3rd para.).

Applicant asserts that "glucose oxidase cannot be considered a pharmacologically active agent" and that [a] "pharmaceutical" is defined as "a medicinal drug" (from Merriam-Webster's Medical Desk Dictionary). Contrary to Applicant's assertion, an enzyme, glucose oxidase is deemed a pharmacologically active agent to one of ordinary skill in the art. Moreover, a pharmacologically active agent taught by Fox et al. is **not** limited to any particular pharmacologically active agents as Applicant acknowledges (see Applicant's remarks at page 9).

Applicant asserts that "none of the cited references contains a teaching or suggestion regarding an expectation of success relating to the combination proposed by the Examiner". One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

In this case, contrary to Applicant's assertion, it is known that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, as the instantly claimed, according to Janssen.

It must be recognized that any judgment on obviousness takes into account knowledge which was generally available and within the level of ordinary skill at the time the claimed invention was made. In this case, it is known at or before the time the claimed invention was made. Therefore, one of ordinary skill in the art would have reasonably expected that a known and art-recognized glucose oxidase used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, would have the same or substantially similar usefulness in the hydrogels of Fox et al., and that combining mutarotase with glucose oxidase would increase the sensitivity of glucose determination according to JP 56137899, with the reasonable expectation of success.

Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The record contains no clear and convincing factual evidence of nonobviousness or unexpected results, i.e., testing data for the claimed invention herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

Claims 1, 4, 9, 14-16 and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keusch et al. (US 5,143,071, PTO-1449) in view of Janssen (EP 539625, PTO-1449) further in view of JP 56137899 (of record) for same reasons of record stated in the Office Action dated October 4, 2004.

Keusch et al. discloses the hydrogel comprising (a) gel forming polymer material such polyethylene oxide (PEO) known as Polyox in an amount of the total weight within the instant claim (see col.7 lines 14-20); (b) water in an amount of the total weight within the instant claim; (c) a pharmacologically active agent; (d) sodium chloride as an electrolyte in an amount 0.1-15 wt % of the total weight overlapping with the instant claimed range; (e) the pH of the hydrogel is about 7 since it was used *in vivo*; (f) a structural support embedded in the hydrogel such as non-woven fabric as the instantly claimed to form into patches; (g) a humectant (see col.4 lines 59-64); (h) a biocide. See col.1 line 46-col.2 line 10; col.6 line 52-col.10 line 19; col.11 line 65-col.17 line 3

Keusch et al. also discloses the same thickness and surface area in a range as the instant claimed (see col.8 line 60-64; col.9 line 6-10). Fox et al. also discloses the process of preparing of the hydrogels by cross-linking provided a cross-linking agent as the instant claimed such as N,N'-mehtylenebisscrylamide (see Table IX at col.17-18).

Keusch et al. does not expressly disclose that a pharmacologically active agent in the hydrogel is glucose oxidase or mutarotase enzyme, the buffer solution, and the particular cross-linking agent.

Janssen discloses that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen

peroxide, used for the same purpose as the instantly claimed (see abstract and col.1 lines 22-35; claim 1).

JP 56137899 teaches that combining mutarotase with glucose oxidase increases the sensitivity of glucose determination and the mechanism. See abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Keusch et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Keusch et al. since it is known that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, as the instantly claimed, according to Janssen.

Therefore, one of ordinary skill in the art would have reasonably expected that a known and art-recognized glucose oxidase used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, would have the same or substantially similar usefulness in the hydrogels of Keusch et al., and that combining mutarotase with glucose oxidase would increase the sensitivity of glucose determination according to JP 56137899.

Response to Argument

Applicant's substantially similar arguments as the first 103(a) rejection over Fox et al. in view of Janssen further in view of JP 56137899, with respect to this rejection

made under 35 U.S.C. 103(a) as being unpatentable over Keusch et al. in view of Janssen further in view of JP 56137899 of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed above.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
April 14, 2005